

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Effect of Transcutaneous electrical nerve stimulation (TENS) in post-episiotomy pain

Protocol summary

Study aim

Determine the effect of transcutaneous electrical nerve stimulation (TENS) on post episiotomy pain

Design

This study is a clinical trial with random allocation that in this study 80 nulliparous women were randomly divided into two control and intervention group.

Settings and conduct

This study is a single blind clinical trial that samples of their belonging to a control group or the intervention are unaware and pain evaluation by a research associate, that unaware of the belonging people to the intervention group or control, will be done. For evaluation of pain severity, the numerical rating scale will be used

Participants/Inclusion and exclusion criteria

Inclusion criteria: nulliparous low-risk pregnancy, singleton pregnancy, gestational age 42-38 weeks, spontaneous vaginal delivery with mediolateral episiotomy, presenting pain in the episiotomy area, no use of analgesics during data collection. Exclusion criteria: side effects of TENS (burns, wounds, skin allergy), Not having epilepsy and mental illness, Not having heart pacemaker and heart disease

Intervention groups

In both groups pain will be determined before intervention. Then in the intervention group transcutaneous nerve stimulation electrode will be insert and will be used for 60 minutes. After that pain will be assessed during four specific time: before applying TENS, 30 minutes, 60 minutes and 120 minutes after removing TENS, at rest and activity (sitting and walking), pain severity, TENS side effects and blood pressure, respiratory rate and pulse rate will be evaluated.

Main outcome variables

Pain; Vital sign; side effect of transcutaneous electrical nerve stimulation (TENS); Mother's satisfaction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171224038034N1**

Registration date: **2018-02-17, 1396/11/28**

Registration timing: **prospective**

Last update: **2018-05-12, 1397/02/22**

Update count: **1**

Registration date

2018-02-17, 1396/11/28

Registrant information

Name

Soma Zakaryaei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 87 3316 1616

Email address

zakaryaei.s@muk.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-20, 1397/01/31

Expected recruitment end date

2018-08-21, 1397/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Transcutaneous electrical nerve stimulation (TENS) in post-episiotomy pain	
Public title	Effect of Transcutaneous Electrical Nerve Stimulation (TENS) in post-episiotomy pain
Purpose	Supportive
Inclusion/Exclusion criteria	
Inclusion criteria:	Nulliparous low-risk pregnancy Singleton pregnancy Gestational age 42-38 weeks spontaneous vaginal delivery (without use of vacuum and forceps) with mediolateral episiotomy presenting pain in the episiotomy area (pain score 4 or more) no use of analgesics during data collection
Exclusion criteria:	side effects of TENS (burns, wounds, skin allergy) Not having epilepsy and mental illness Not having heart pacemaker and heart disease
Age	No age limit
Gender	Female
Phase	N/A
Groups that have been masked	Participant
Sample size	Target sample size: 80
Randomization (investigator's opinion)	Randomized
Randomization description	Using Blocked Randomization for randomization
Blinding (investigator's opinion)	Single blinded
Blinding description	Samples of their belonging to a control group or the intervention are unaware and pain evaluation by a research associate, that unaware of the Belonging to the intervention group or control people will be done
Placebo	Used
Assignment	Parallel
Other design features	
Secondary Ids	empty
Ethics committees	
1	
Ethics committee	
Name of ethics committee	Ethic committee of Kurdistan University of Medical Sciences
Street address	Kurdistan University of Medical Sciences , Pasdaran

Street, Sanandaj	
City	Sanandaj
Province	Kurdistan
Postal code	66166
Approval date	2018-02-04, 1396/11/15
Ethics committee reference number	IR.MUK.REC.1396/318
2	
Ethics committee	
Name of ethics committee	Ethic committee of Kurdistan University of Medical Sciences
Street address	Kurdistan University of Medical Sciences , Pasdaran Street, Sanandaj
City	Sanandaj
Province	Kurdistan
Postal code	66166
Approval date	2018-02-18, 1396/11/29
Ethics committee reference number	IR.MUK.REC.1396/365
Health conditions studied	
1	
Description of health condition studied	Pain after episiotomy
ICD-10 code	G89.18
ICD-10 code description	Other acute postprocedural pain
Primary outcomes	
1	
Description	Pain severity after episiotomy
Timepoint	evaluating pain severity in before applying TENS, 30 minutes, 60 minutes and 120 minutes after removing TENS, at rest and activity (sitting and walking)
Method of measurement	NRS
Secondary outcomes	empty

Intervention groups

1

Description

Intervention group: The transcutaneous electrical nerve stimulation electrodes, 6-24 hours after episiotomy, will be inserted in parallel, near the episiotomy, in the region of the pudendal and genitofemoral nerve and device will be on for 60 minutes, after that pain will be assessed again during four specific time: before applying TENS, 30 minutes, 60 minutes and 120 minutes after removing TENS, at rest and activity (sitting and walking).

Category

N/A

2

Description

Control group: In this group electrodes will be inserted at the same place as intervention group but device will be off and the evaluation is as the same.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat hospital of Sanandaj, Kurdistan University of Medical Sciences

Full name of responsible person

Seyedeh Soma Zakaryae

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Kurdistan University of Medical Sciences, Sanandaj

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Web page address

<http://www.muk.ac.ir/Muk.aspx>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sanandaj University of Medical Sciences

Full name of responsible person

Dr Rezaei

Street address

Kurdistan University of Medical Sciences Pasdaran street, Sanandaj

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+98 87 3366 0092

Email

ss.zakaryae@gmail.com

Web page address

<http://www.muk.ac.ir/Muk.aspx>

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Sanandaj University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Sanandaj University of Medical Sciences

Full name of responsible person

Seyedeh Soma Zakaryae

Position

Student Masters

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Position

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available